

6

UTR-103XC1

Remarks

Claims 1, 3-13 and 22-32 are pending in the subject application. Applicants acknowledge that claims 2, and 14-20 have been canceled from further consideration. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1,3-13, and 22-32 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested. Applicants respectfully submit that this amendment will not necessitate a new search or raise new issues for consideration by the Examiner.

Claims 1, 3-13 & 21 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fuhrman *et al* (as cited by applicant). Additionally, claims 25-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fuhrman *et al*, in view of Stacey *et al*. (5,173,424) or Gillette *et al*., (J. Bacteriology, May 1996, pp 2757-2766) (both cited by applicant). At the outset, Applicants wish to thank Examiner Lankford for the re-transmittal of the office action in this matter. Applicants also believe that a typographical error is present as the rejection over Fuhrmann *et al*. is presumably under section 102(b) as the reference is non-patent literature. Applicants note that the rejection appears to be predicated on the doctrine of inherency as the reference is silent on the effects of iron on CDF. Applicants again respectfully traverse.

As the Patent Office is aware, anticipation (under the doctrine of inherency) is to be distinguished from accidental or unwitting anticipation. For example, the accidental attainment of a claimed invention without recognition of the result or how it was achieved has been held to not constitute anticipation (*see Tilghman v. Proctor*, 102 U.S. 707, 26 L.Ed. 279 (1880)). In this decision, the Supreme Court ruled that anticipation could not be found where the prior art process was not directed to the process claims at issue and because the product produced by the method was accidentally and unwittingly produced, without knowledge of what was done or how it was done. In *Eibel Process Co. v. Minnesota & Ont. Paper Co.*, 261 U.S. 45 (1923), the Supreme Court also held that held that accidental results, unintentional and unappreciated, did not constitute anticipation. Other decisions indicate that cases applying this doctrine have consistently held that what is required is true fortuitousness, as in the example of a chemical being produced as a side effect to no one's knowledge (*see Clements Industries Inc. v. A. Meyers & Sons Corp.*, 12 USPQ2d 1874, 1879 (DC

JAUTR103XC1\UTR-103XC1 AFRresponse.doc\DNB\ssa

SNY 1989) citing *Tilghman v. Proctor*, 102 U.S. 707 (1881)). Additionally, if a claimed method comprises steps identical to those of a method practiced in the prior art, and the same result would have been achieved in the prior art method, the accidental or unwitting achievement of that result cannot constitute anticipation (see *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); see also *In re Felton*, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973) (accidental or unwitting duplication of an invention cannot constitute an anticipation.). Furthermore, an anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

Applying these concepts to the presently claimed invention, it is clear that the reference fails to describe the claimed subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. Indeed, the Office Action indicates that the cited reference fails to teach CDF and the role of iron in its regulation. Additionally, as indicated in *In re Marshall*, even if a claimed method comprises steps identical to those of a method practiced in the prior art, and the same result would have been achieved in the prior art method, the accidental or unwitting achievement of that result cannot constitute anticipation. As argued previously, no extrinsic evidence has been provided that would demonstrate that persons of ordinary skill in the art would have recognized the effects of iron addition, to growth medium, on the levels of CDF in nodulation inoculants. Indeed, it appears that Applicants are the first to establish a link between CDF, the nodulation efficiency of *Bradyrhizobium japonicum* cultures, and the role of iron in this relationship. Thus, it is respectfully submitted that the reference fails to teach a method of producing a nodulation inoculant containing reduced amounts of cell density factor (CDF) comprising the addition of iron to growth medium for a nodulation inoculant in amounts sufficient to reduce the concentration of CDF. Accordingly, it is respectfully submitted that Fuhrmann *et al.* fail to anticipate the claimed invention because: 1) the claimed subject matter was not described with sufficient clarity to establish that the subject matter existed; 2) that existence of the claimed subject matter was not recognized by persons skilled in the art on the basis of the teachings of Fuhrmann *et al.*; and 3) that even if identical steps to those claimed were

known in the prior art, the accidental or unwitting achievement of the claimed composition containing reduced amounts of CDF cannot constitute anticipation. Thus, it is respectfully submitted that the subject invention (claims 1, 3-13, and 21-32) is not anticipated, nor rendered obvious, by Fuhrmann *et al.*

Applicants further submit, based on the teachings of the reference, that one skilled in the relevant art would not have recognized the reference to suggest or teach that the addition of iron to inoculant cultures would have a beneficial effect. For example, Fuhrmann *et al.* teach: "Addition of ferric hydroxide to the vermiculite had no significant effect on nodule occupancy for any *B. japonicum* treatment in the absence of applied rhizosphere bacteria" (page 110, column 2, lines 21-24). Fuhrman *et al.* also teach: "Addition of iron to the vermiculite reduced the ability of the rhizosphere isolates to alter nodule occupancy, relative to that for non-amended vermiculite" (emphasis added, page 110, column 2, lines 10-12). Thus, it is respectfully submitted that the addition of iron to *Bradyrhizobium japonicum* cultures does not increase the nodulation efficiency of the *B. japonicum* cultures (see, for example, claims 22 and claims 24-32), rather, the addition of iron decreases the nodulation efficiency of the cultures or has no effect on their nodulation efficiency. Indeed, one skilled in the art would have expected a reduction in the nodulation efficiency of a nodulation inoculant when iron was added to the inoculant cultures in view of the teachings of Fuhrmann *et al.* Accordingly, it is respectfully submitted that the Fuhrmann neither anticipates, nor renders obvious, the claimed invention.

It is further submitted that one skilled in the relevant art would not have recognized that iron had any role in nodulation activity of *B. japonicum* or that iron reduces the production of CDF by *B. japonicum* in culture or in a nodulation inoculant. Indeed, the skilled artisan would have, likely, recognized: 1) that the addition of other rhizosphere bacteria was necessary to increase nodule occupancy by *B. japonicum*; 2) that the addition of iron in the absence of additional rhizosphere bacteria did not significantly effect the nodulation efficiency of *B. japonicum* strains; and 3) that the addition of iron to vermiculite actually reduced the ability of rhizosphere isolates to alter nodule occupancy of *B. japonicum* strains. Again, reconsideration and withdrawal of the anticipation and obviousness rejections is respectfully requested.

The Office Action further states that even if the reference fails to anticipate the claimed

subject matter, the invention remains obvious in view of Fuhrman's teachings as it clearly establishes that iron concentration in bradyrhizobium medium is a result effective variable and, as such, would have been routinely optimized by one skilled in the art to effect the growth of the bacterium and its nodulating activity. Applicants again respectfully traverse. It is respectfully submitted that a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (C.C.P.A. 1977). In the case of the instant invention, it is respectfully submitted that one skilled in the art would not have recognized iron levels to be such a result-effective variable. Again, Fuhrmann *et al.* teach that the addition of iron (ferric hydroxide) had no effect on nodule occupancy by *B. japonicum* strains in the absence of the additional application of other rhizosphere isolates (see page 110, column 2, lines 21-24). Indeed, the addition of iron in the presence of these rhizosphere isolates actually reduced the ability of the rhizosphere isolates to alter nodule occupancy of *B. japonicum* strains (page 110, column 2, lines 10-12). Thus, it is respectfully submitted that one skilled in the art would have recognized that the co-inoculants used in the teachings of the reference were more likely a result-effective variable than the addition of iron in view of the teachings of the reference, especially in view of the teachings of the reference discussing the negative effect iron had on the ability of the rhizosphere isolates to alter nodule occupancy. Accordingly, it is respectfully submitted that one skilled in the art would not have been motivated to optimize iron concentrations in the medium; rather, one of ordinary skill in the art, in view of the teachings of the reference, would have been motivated to omit iron from any media in view of the negative effects it appeared to have on the ability of rhizosphere isolates alter nodule occupancy of *B. japonicum* strains and in view of the teaching iron had no effect on nodule occupancy by *B. japonicum* strains. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further submit that the cited prior art also fails to teach the limitations of the independent and various dependent claims. For example, the prior art fails to teach: a) the addition of iron to: growth medium for a nodulation inoculant; or liquid growth medium; b) the addition of iron to growth medium concomitantly with, or after, the nodulation inoculant is added to said medium; the addition of a single strain or species of nodulating bacteria to liquid growth medium;

J:\UTR103XC1\UTR-103XC1 AFResponse.doc\DNB/ssg

10

UTR-103XC1

and/or increases in the nodulation efficiency of nodulation inoculants that are associated with the growth of the inoculants in iron containing medium (see, for example, the limitations of claims 1, 6, 9, and newly added claims 25-32). Accordingly, reconsideration and withdrawal of the rejection as applied to these claims is respectfully requested.

Turning to the rejection as applied to the product-by-process claim of claim 21, it is respectfully submitted that the claimed composition possesses novel and non-obvious differences as compared to nodulation inoculants of the prior art or those taught by Fuhrmann *et al.* For example, the claimed composition comprising a nodulation inoculant would exhibit increased nodulation efficiency (and increased nodule occupancy) by virtue of having decreased levels of quorum factor (CDF) as compared to the inoculant produced by Fuhrmann *et al.* or those of the prior art (see Example 7, paragraphs 2-3). Indeed, the compositions of Fuhrmann *et al.* that contain iron are taught to have no effect on nodule occupancy by *B. japonicum* strains in the absence of the additional application of other rhizosphere bacteria (see page 110, column 2, lines 21-24) or the addition of iron in the presence of these rhizosphere bacteria actually reduced the ability of the rhizosphere isolates to alter nodule occupancy of *B. japonicum* strains (page 110, column 2, lines 10-12). Accordingly, nodulation inoculants produced according to the claimed methods would have an increased ability to nodulate plant roots as compared to the nodulation inoculants of the prior art because these compositions contained reduced amounts of CDF. Such differences are not taught, suggested, nor rendered obvious by the prior art and reconsideration and withdrawal of the rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

JAUTRM103XC1UTR-103XC1 AIPResponse.doc/DNH/ssd

11

UTR-103XC1

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

PCF/ssa